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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,999	01/20/2004	Mark Harbaugh	50642/287728	1647
30559 7590 05/20/2008 CHIEF PATENT COUNSEL SMITH & NEPHEW, INC. 1450 BROOKS ROAD MEMPHIS, TN 38116				
EXAMINER EREZO, DARWIN P				
ART UNIT		PAPER NUMBER		
3773				
MAIL DATE		DELIVERY MODE		
05/20/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/760,999

**Applicant(s)**

HARBAUGH ET AL.

**Examiner**

Darwin P. Erezzo

**Art Unit**

3773

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date 10/15/07, 12/7/07 and 4/29/08.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement(s) (IDS) submitted on 10/15/07, 12/7/07 and 4/29/08 have been received and made of record. Note the acknowledged form PTO-1449 enclosed herewith.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,715,836 to Kliegis et al.

Kliegis discloses a method of performing an incision using a computer aided surgical navigation system, the system comprising a sensor adapted to sense the position and orientation of at least one surgical reference associated with a structure to be referenced (col. 4, line 66-col. 5, line 4; col. 6, line 3-6); and computer functionality 1, the method of guiding the surgical incision comprising:

associating at least one first surgical reference with a portion of an individual's bony anatomy and skin proximate the bony anatomy (col. 4, line 66-col. 5, line 4);

registering the position and orientation of the portion of the individual's bony anatomy and skin proximate the bony anatomy with the computer aided surgical navigation system such that the computer functionality can generate information

corresponding to the position and orientation of the individual's bony anatomy and skin proximate the bony anatomy by receiving information from the sensor sensing the position and orientation of the first surgical reference, and calculating a suggested incision path and length based upon the information generated by the computer functionality (col. 5, lines 4-12);

associating at least one second surgical reference with an incision device (col. 6, line 40); and

registering the position of the incision device with the computer aided surgical navigation system such that the computer functionality can generate information corresponding to the position of the incision device by receiving information from the sensor sensing the position and orientation of the second surgical reference; and using the incision device in the performance of the incision, wherein the computer aided surgical navigation system provides guidance based on comparing the suggested incision path and length with the information corresponding to the position and orientation of the incision device as generated by the computer functionality (col. 6, lines 40-55);

wherein the computer aided surgical navigation system providing guidance further comprises a display 6; wherein displaying the suggested incision path and length and the position of the incision device further comprises a semi-transparent display displaying the suggested incision path and length and the position of the of the incision device or a monitor displaying the suggested incision path and length and the position of the of the incision device (col. 5, lines 38-49);

Art Unit: 3773

wherein a visual or audible feedback is provided if the incision device deviates from the suggested incision (col. 6, lines 47-50);

wherein an image of the suggested incision is projected onto the individual (col. 6, lines 14-24);

wherein the incision is used to access the interior of the individual to install an orthopaedic implant; and installing the orthopaedic implant (col. 6, lines 62-67).

#### ***Response to Arguments***

4. Applicant's arguments filed 1/16/08 have been fully considered but they are not persuasive. The applicant argued that Kliegis fails to disclose a sensor adapted to sense the position and orientation of at least one surgical reference associated with a structure to be referenced. This argument is not persuasive because Kliegis discloses in col. 4, line 40-col. 5, line 4) that:

"To plan and prepare for a surgical operation for removing a tumor from a human cranium, a series of sectional images of the cranium is first produced with the aid of computed tomography and/or nuclear magnetic resonance Tomography. The images in each case show one layer, and the layers lie parallel and at a short distance one above the other. The measurement data determined by tomography is conveyed to a DPU 1, where, after an operation site has been established, a three-dimensional desired image of said site 8, i.e. of the cranial region presenting the tumor, is created from the measurement data by appropriate software. In addition, further structural data obtained, for example, by evaluating the results of ultrasound, X-ray, or holographic examinations of the cranium can then be input into the DPU.

As shown above, the orientation of the body (which is viewed as a surgical reference) is sensed via computer tomography and/or nuclear magnetic resonance Tomography (which would inherently have sensors). Furthermore, as stated above, this sensed orientation (or surgical reference) is conveyed to a computer to provide a

suggested incision path. It is also noted that a second sensor (the video camera) is used to monitor the position of the cutting device and that the claims do not limit the surgical navigation system from having a second sensor.

***Conclusion***

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3773

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezol/  
Primary Examiner, Art Unit 3773